IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
EMCURE PHARMACEUTICALS LTD.,	)	
HERITAGE PHARMACEUTICALS INC.,	)	
and HERITAGE PHARMA LABS INC.	)	
	)	
Defendants.	)	
	)	
	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Amgen Inc. ("Amgen") by way of Complaint against Defendants Emcure Pharmaceuticals Ltd. ("Emcure"), Heritage Pharmaceuticals Inc. ("Heritage"), and Heritage Pharma Labs Inc. ("Heritage Labs") (collectively, "Defendants") alleges as follows:

PARTIES

1. Amgen is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry.

2. Upon information and belief, Defendant Emcure is an Indian corporation, having a principal place of business at Emcure House, T184, M.I.D.C, Bhosari, Pune, 411026, Maharashtra, India.

3. Upon information and belief, Defendant Heritage is a Delaware corporation, having a principal place of business at One Tower Center Boulevard, Suite 1700,

East Brunswick, New Jersey, 08816. Upon information and belief, Heritage is a wholly-owned subsidiary of Emcure.

4. Upon information and belief, Defendant Heritage Labs (f/k/a Emcure Pharmaceuticals USA Inc.) is a New Jersey corporation, having a principal place of business at 21 Cotters Lane # B, East Brunswick, New Jersey, 08816. Upon information and belief, Heritage Labs is a wholly-owned subsidiary of Emcure.

5. Upon information and belief, Heritage and Heritage Labs are agents or affiliates of Emcure, and are acting as agents of Emcure. with respect to Abbreviated New Drug Application ("ANDA") No. 210359.

6. Upon information and belief, Defendants regularly act in concert to transact business throughout the United States and within Delaware, including but not limited to marketing, distribution, sales, and/or offers to sell generic drugs.

NATURE OF THE ACTION

7. This is a civil action for infringement of U.S. Patent No. 9,375,405 (the "'405 patent") (Exhibit A) under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271(e)(2), 271(a), 271(b), and 271(c), and for a declaratory judgment of infringement of the '405 patent under 28 U.S.C. §§ 2201 and 2202. This action arises out of Defendants' submission of ANDA No. 210359 seeking approval to manufacture, use and/or sell cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) ("Defendants' ANDA products").

JURISDICTION AND VENUE

8. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has

jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. This Court has jurisdiction over Emcure because, *inter alia*, upon information and belief, Emcure directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA products. Upon information and belief, Emcure acted in concert with and/or with the assistance of Heritage and Heritage Labs to file ANDA No. 210359. Upon information and belief, Defendants, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA products in the United States, including in Delaware, upon approval of ANDA No. 210359, and will derive substantial revenue from the use or consumption of Defendants' ANDA products in the State of Delaware.

10. In the alternative, this Court has jurisdiction over Emcure because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over Emcure because, *inter alia*, this action arises from actions of Emcure directed toward Delaware, and because Emcure has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Emcure regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through affiliates. Upon information and belief, Emcure derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

11. This Court also has jurisdiction over Emcure because, *inter alia*, upon information and belief, Emcure has previously been sued in this jurisdictional district without

objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertions of counterclaims in suits brought in Delaware. *See e.g.*, *Bristol-Myers Squibb Co. et al. v. Emcure Pharms. Ltd.*, Civil Action No. 17-cv-00402 (D. Del.); *Genzyme Corp. et al. v. Emcure Pharms. USA, Inc. et al.*, Civil Action No. 14-cv-05975 (D. Del.).

12. This Court has jurisdiction over Heritage because, *inter alia*, upon information and belief, Heritage is a Delaware corporation, is registered with the Delaware Department of State, Division of Corporations to do business as a domestic corporation in Delaware under file number 3987766, and has a registered agent for service of process in this judicial district (Corporation Service Company). Upon information and belief, Heritage directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA products. Upon information and belief, Heritage acted in concert with and/or with the assistance of Emcure and Heritage Labs to file ANDA No. 210359. Upon information and belief, Defendants, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA products in the United States, including in Delaware, upon approval of ANDA No. 210359, and will derive substantial revenue from the use or consumption of Defendants' ANDA products in the State of Delaware.

13. This Court has jurisdiction over Heritage Labs because, *inter alia*, upon information and belief, Heritage Labs directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA products. Upon information and belief, Heritage Labs acted in concert with and/or with the assistance of Emcure and Heritage to file ANDA No. 210359. Upon information and belief, Defendants, acting in concert and/or as agents of one another, will

market, distribute, and/or sell Defendants' ANDA products in the United States, including in Delaware, upon approval of ANDA No. 210359, and will derive substantial revenue from the use or consumption of Defendants' ANDA products in the State of Delaware.

14. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

THE PATENT-IN-SUIT

15. On June 28, 2016, the '405 patent, titled "Rapid Dissolution Formulation of a Calcium Receptor-Active Compound," was duly and legally issued by the United States Patent and Trademark Office ("PTO").

16. The '405 patent is assigned to Amgen and Amgen is the owner of the '405 patent.

17. Amgen is the holder of an approved New Drug Application ("NDA") No. 21-688 for cinacalcet hydrochloride tablets which the U.S. Food and Drug Administration ("FDA") approved on March 8, 2004. Cinacalcet hydrochloride is a calcium receptor-active compound.

18. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

19. The '405 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for NDA No. 21-688.

20. The claims of the '405 patent are directed to pharmaceutical compositions comprising cinacalcet hydrochloride.

BACKGROUND ON SENSIPAR®

21. Cinacalcet hydrochloride is the active ingredient in SENSIPAR®, a medication marketed and sold in tablet form by Amgen. Amgen received FDA approval to market SENSIPAR® (cinacalcet hydrochloride) on March 8, 2004 to treat secondary hyperparathyroidism ("HPT") in patients with chronic kidney disease ("CKD") on dialysis and hypercalcemia in patients with parathyroid carcinoma.

22. Secondary HPT is a condition that is caused when the parathyroid glands located in the neck produce too much parathyroid hormone in response to low blood calcium and is associated with CKD patients. SENSIPAR® helps to lower the amount of parathyroid hormone, calcium, and phosphorus concentrations in the blood.

23. SENSIPAR® is also indicated for use in lowering calcium levels in the blood for patients with parathyroid cancer. Patients with parathyroid cancer can develop severe hypercalcemia (an excessive amount of calcium in the blood). Removal of the parathyroid was the only available therapy for parathyroid cancer before SENSIPAR®.

24. SENSIPAR® is a first-in-class molecule developed by scientists to treat an unmet need in patients suffering from secondary HPT and parathyroid carcinoma.

25. On February 25, 2011, Amgen also received FDA approval to market SENSIPAR® to treat severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy.

26. For SENSIPAR®, the Orange Book currently lists, *inter alia*, the '405 patent and its parent, U.S. Patent No. 7,829,595 ("the '595 patent").

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENT-IN-SUIT

27. Upon information and belief, Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

28. Upon information and belief, Defendants reviewed certain commercial and economic information regarding Amgen's SENSIPAR® and decided to file an ANDA seeking approval to market a generic version of SENSIPAR®.

29. Amgen received a letter dated July 25, 2018 from Emcure notifying Amgen that Emcure had filed ANDA No. 210359 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to commercially manufacture, use, sell, and/or import Defendants' ANDA products. ANDA No. 210359 seeks FDA approval to market Defendants' ANDA products prior to the expiration of the '405 patent.

30. The stated purpose of Emcure's July 25, 2018 letter was to notify Amgen that ANDA No. 210359 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") alleging that the claims of the '405 patent were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA products. Included in the July 25, 2018 letter was a detailed statement of the factual and legal basis for Emcure's Paragraph IV Certification.

31. Upon information and belief, Defendants were aware of the '405 patent when Emcure notified Amgen of its Paragraph IV Certification of the '405 patent.

32. Amgen commenced this action within 45 days of receipt of the letter.

FIRST CLAIM FOR RELIEF

33. Amgen incorporates and realleges paragraphs 1-32 above, as if set forth specifically here.

34. Upon information and belief, Emcure filed ANDA No. 210359 with the FDA under the provisions of 21 U.S.C. § 355(j).

35. Upon information and belief, Emcure's ANDA No. 210359 seeks FDA approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA products (generic cinacalcet hydrochloride tablets, EQ 30 mg, EQ 60 mg, and EQ 90 mg base) before the expiration of the '405 patent.

36. On July 26, 2018, Amgen received a letter from Emcure dated July 25, 2018, purporting to be a Notice of Certification for ANDA No. 210359 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

37. Emcure's letter alleges that the active ingredient in Defendants' ANDA products for which it seeks approval is cinacalcet hydrochloride.

38. Upon information and belief, Emcure has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '405 patent are invalid, not infringed and/or unenforceable.

39. Defendants' submission of ANDA No. 210359 to obtain approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA products prior to the expiration of the '405 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, Defendants' ANDA products would infringe, either literally or under the doctrine of equivalents, at least claim 1 of the '405 patent.

41. Upon information and belief, Amgen is entitled to full relief from Defendants' acts of infringement of the '405 patent under 35 U.S.C. § 271(e)(4).

SECOND CLAIM FOR RELIEF

42. Amgen incorporates and realleges paragraphs 1-41 above, as if set forth specifically here.

43. Upon information and belief, Defendants have made substantial preparations to sell Defendants' ANDA products.

44. Upon information and belief, Defendants intend to commence sale of Defendants' ANDA products immediately upon receiving approval from the FDA.

45. Upon information and belief, the manufacture, use, sale, offer for sale, and importation of Defendants' ANDA products, once approved by the FDA, will infringe, either literally or under the doctrine of equivalents, induce and/or contribute to the infringement of at least claim 1 of the '405 patent under 35 U.S.C. § 271(a), (b) and/or (c).

46. Amgen will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Amgen has no adequate remedy at law.

47. An actual controversy exists relating to Defendants' threatened infringement of the '405 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Amgen respectfully requests the following relief:

A. A judgment that the claims of the '405 patent are not invalid, are not unenforceable, and are infringed by Defendants' submission of ANDA No. 210359 under 35 U.S.C. § 271 (e)(2)(A), and that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA products prior to the expiration of the '405 patent will constitute an act of infringement of the '405 patent.

B. An order under 35 U.S.C. § 271 (e)(4)(A) that the effective date of any FDA approval of ANDA No. 210359 shall be a date that is not earlier than the expiration date of the '405 patent, inclusive of any extensions.

C. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendants' ANDA products until after the expiration of the '405 patent, including any extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled.

D. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Amgen costs, expenses, and disbursements in this action, including reasonable attorney fees.

E. Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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